

EXHIBIT B

ATTORNEY DOCKET NO. RTI-104IB
01915/13971US03

IN THE UNITED STATES
PATENT AND TRADEMARK OFFICE

In the Application of:

Grooms, *et al.*

Serial No.: 09/722,205

Filed: November 25, 2000

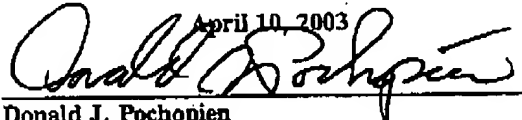
For: "Intervertebral Spacers"
(As Amended)

Group Art Unit: 3732

Examiner: Eduardo C. Robert

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on this date:

April 10, 2003

Donald J. Pochopien
Registration No. 32,167
Attorney for Applicants

SECOND PRELIMINARY AMENDMENT and
ELECTION OF INVENTION UNDER 35 U.S.C. § 121

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In response to the Official Action of 01/14/03, for which a response was due 02/14/03, now extended two (2) months to 04/14/03, the Applicants respectfully request that the Examiner make the following amendments to the specification and the claims in addition to considering the Applicants' election of invention.

In the Title:

Please delete the title and substitute therefor the following:

-- Intervertebral Spacers --

In the Specification:

At the top of page 1 of the specification, immediately below the title, please insert the following paragraph:

-- This application is a continuation of USSN 09/701,933, now pending, which is the National Stage of International Application No. PCT/US98/17769, filed 08/27/1998, which is a continuation-in-part of USSN 08/920,630, filed 08/27/1997, now abandoned.--

In the claims:

Please cancel claims 1-44.

Please add new claims 45-51:

45. (New) A polygonal spinal spacer for engagement between vertebrae, comprising: a polygonal cortical bone portion having a first end, an opposing second end, a superior face defining a superior vertebral engaging surface and an inferior face defining an inferior vertebral engaging surface; and at least one of said vertebral engaging surfaces defining a first set of migration resistant projections, ribbing or teeth, each of said projections, ribbing or teeth defining a pocket therebetween for trapping vertebral bone, said cortical bone portion having an internal canal extending between opposing faces thereof.

46. (New) The spacer of claim 45, wherein said polygonal cortical bone portion is a composite.

47. (New) The spacer of claim 46, wherein said composite comprises two stacked pieces of cortical bone.

48. (New) The spacer of claim 46, wherein said composite comprises two pieces of cortical bone in juxtaposition to one another.

49. (New) The spacer of claim 46, wherein said canal has an appropriately shaped cancellous bone portion fitted therein.

50. (New) The spacer of claim 46, wherein said polygon has a substantially diamond shaped external profile.

51. (New) The spacer of claim 46, wherein the cortical bone of said cortical bone portion is allograft cortical bone.

A copy of all pending claims (claims 45-51) is attached hereto as Exhibit A.

ELECTION OF SPECIES

In the Official Action of 01/14/03, the Patent Office requested that the Applicants elect an invention under 35 U.S.C. 121. In response, the Applicants elect to prosecute the invention of Group I, corresponding to claims 1-28 and 32-44, which are drawn to "a spinal spacer". In addition, the Applicants elect to prosecute the species from subgroup IX, corresponding to the spinal spacer of Figures 12A-12D. The Applicants respectfully submit that newly submitted claims 45-49 and 51 are generic for the spinal spacers of subgroups I-XIV. Newly submitted claim 50 is generic for the species in subgroups IX-XVI.

REMARKS

The amendment to the specification, claiming priority, is proper without the filing of a petition under 37 C.F.R. § 1.78(a)(3) because the present application, which was filed on November 25, 2000, is an "application filed under 35 U.S.C. 111(a) before November 29, 2000" [37 C.F.R. § 1.78(a)(2)(ii)(B)], such that the time periods recited in 37 C.F.R. § 1.78(a)(2)(ii) do not apply.

The amendment adding claims 45-51 does not add new matter. Newly added claim 45, which is generic for the embodiments in the figures, is directed to "a

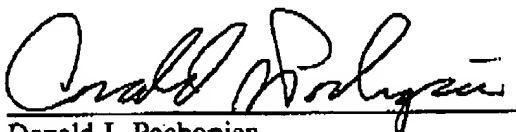
polygonal spinal spacer for engagement between vertebrae, comprising: a "polygonal cortical bone portion having a first end, an opposing second end, a superior face defining a superior vertebral engaging surface and an inferior face defining an inferior vertebral engaging surface; and at least one of said vertebral engaging surfaces defining a first set of migration resistant projections, ribbing or teeth, each of said projections, ribbing or teeth defining a pocket therebetween for trapping vertebral bone, said cortical bone portion having an internal canal extending between opposing faces thereof." Support for the spinal spacer being a polygon is found throughout the specification, including in Figures 12A, 13A, 14A, 15A, 16A and 17A. Support for at least one of the opposing surfaces of the cortical bone having "projections, ribbing or teeth" for engaging the vertebrae is found throughout the specification, including at page 9, lines 5-9 ("an external feature may be machined into the upper and lower surfaces to prevent backing out of the implant upon insertion into the intervertebral space. This may be achieved by a number of means, such as by machining annular rings, indentations and **projections, ribbing or teeth** into the upper, lower or both surfaces of the implant"); emphasis added in bold. Support for the cortical bone portion having an "internal canal" is found throughout the specification, including at Figures 1A-1D, 6D-E, 6G-H, 12A, 13A, 14A, 15A, 16A and 17A, and at page 9, lines 25-26 ("The implant has a wall thickness 101, a length 103, a width 102, and an internal canal 104") Claim 46, which is directed to the spacer of claim 45, wherein said polygonal cortical bone portion is a "composite" of multiple parts is supported throughout the specification, including at page 17, lines 4-5 ("two implant blanks of known height are selected such that a unitary implant composed of both starting implants can be produced."); and at page 17, lines 8-11 ("Pins, composed of cortical bone. . . are then impelled into the holes in the implants such that the implants are formed into a unitary body by these pins."). Claim 47, which is directed to the spacer of claim 46, wherein the composite comprises "two stacked pieces of cortical bone," is supported throughout the specification, including at page 16, lines 29-30 ("In figure 7, there is shown a further aspect of this invention in which an implant . . . is further machined so as to allow stacking thereof . . ."). Claim 48, which is directed to

the spacer of claim 46, wherein the composite comprises two pieces of cortical bone in "juxtaposition to one another," is supported throughout the specification, including at page 17, lines 13-14 ("In figure 7B, there is shown the juxtaposition of two implants 700A and 700B, with the drilled holes 701-704 in register to receive pins for maintaining the implants in register"); and at page 17, lines 29-30 ("The two halves of the implant are brought into juxtaposition to form a unitary implant"). Claim 49, which is directed to the spacer of claim 46, wherein said canal has an appropriately shaped cancellous bone portion fitted therein, is supported throughout the specification, including at Figs 13A, E and F, at Figs 15 A, E and F, at Figs 17 A, E and F, and at page 21, lines 1-10. Claim 50, which recites that the polygon of claim 46 has a "substantially diamond shaped external profile," is supported throughout the specification, including at page 20, lines 27-29 ("[a]s can be seen, the implant produced according to this aspect of the invention has a substantially diamond shaped external profile. . . ."). Finally, claim 51, which is directed to the spacer of claim 46, wherein the cortical bone of said cortical bone portion is "allograft" cortical bone, is supported throughout the specification, including at page 2, lines 20-21 ("the implant is derived from allograft or autograft cortical bone sources . . .") For all these reasons, the amendments to the specification and claims do not add new matter.

Respectfully submitted,

MCANDREWS, HELD & MALLOY, LTD.

By:



Donald J. Pochopien
Registration No. 32,167
Attorney for Applicants
500 West Madison Street
34th Floor
Chicago, Illinois 60661
(312) 775-8133

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